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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,655	07/31/2003	Alan Leslie Cripps	CRIP3001C2/REF	9488

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EXAMINER

HAGHIGHATIAN, MINA

ART UNIT PAPER NUMBER

1616

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/630,655

Applicant(s)

CRIPPS ET AL.

Examiner

Mina Haghighatian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-27, 29-31 and 33-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-27, 29-31 and 33-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the Amendments and Remarks filed on 09/29/05.

Claim 7 is cancelled and claims 2 and 10 are amended. Accordingly claims 1-6, 8-27, 29-31 and 33-38 are pending.

NOTE: The pages containing claims and amendments filed on 09/29/05 state an incorrect application number (10/866,771) on top.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-6, 8-27, 29-31 and 33-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al in view of Weers et al (6,309,623).

Davis et al teach aerosol solutions for drug delivery, where the system contains water, ethanol and propylene glycol. An important finding for Davis et al was that with steroidal compounds the solubility of the drug in the vehicle was of great importance. The presence of ethanol should give the vehicle solvent characteristics without changing physical characteristics (see introduction on page 85). Davis uses flunisolide as an example of a steroidal compound and shows that addition of ethanol improve delivery, and concludes that propylene glycol-ethanol and water systems show that output increases as the ratio of ethanol to propylene glycol increases (see page 91-92). Table 1 on page 87 discloses data for water-propylene glycol systems, which includes

various concentrations for ingredients such as propylene glycol. The said concentration ranges include 5%, which is very close to claimed 3% range.

Davis et al, while disclosing steroidal compounds as a genus, lack disclosure on fluticasone as a species.

Weers et al disclose stabilized formulations for use in metered dose inhalers for aerosol delivery to the respiratory systems. The formulations are generally in a dispersion in a medium comprising hydrofluoroalkane propellants (see abstract and col. 3, lines 53-67). Weers et al also disclose a variety of active agents that can be used in the said formulations and list flunisolide and fluticasone propionate as suitable candidates for the said formulations (col. 19, lines 55-67).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have substituted one steroidal compound, fluticasone, as disclosed by Weers et al, with another steroidal compound, flunisolide as disclosed by Davis et al, and have produced effective and stable formulations for delivery. In other words, one of ordinary skill in the art would have been motivated to practice the teachings of Davis using other active agents, since Davis is clearly disclosing advantages of the solutions for aerosol delivery.

Claims 1-6, 8-27, 29-31 and 33-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Otterbeck et al (5,914,122) in view of Weers et al (6,309,623).

Otterbeck et al disclose a stable budesonide solution where budesonide is dissolved in a solvent which may be water, an alcohol such as ethanol, isopropanol or propylene glycol or mixtures thereof (see abstract and col. 2, lines 7-21). It is also disclosed that the solvents could be ethanol, isopropanol, glycerol, polyethylene glycol, propylene glycol, etc (col. 3, line 66 to col. 4, line 4). Otterbeck discloses that the solvent system (water/ethanol/propylene glycol) comprises from 0.001 to 0.1% by weight of the active agent (claim 22). Otterbeck lacks disclosure on fluticasone propionate as the active agent.

Weers et al, discussed above, discloses fluticasone, flunisolide and budesonide as suitable active agents for aerosol delivery of the said formulations.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have substituted one steroidal compound, fluticasone, as disclosed by Weers et al, with another steroidal compound, budesonide as disclosed by Otterbeck et al, and have produced effective and stable formulations for delivery to respiratory system. In other words, one of ordinary skill in the art would have been motivated to prepare solution formulations as disclosed by Otterbeck et al using other active agents, since Otterbeck et al clearly disclose advantages of the solutions for aerosol delivery.

Response to Arguments

Applicant's arguments filed 09/29/05 have been fully considered but they are not persuasive.

Applicant argues that Davis et al is disclosing an aqueous system, whereas the instant claims are to a non-aqueous system (see page 8, lines 11-14 of Remarks). This is not commensurate with the scope of claims. Instant claims use the open ended language of "comprising" and do not exclude water from the formulation. Furthermore the claims do not recite the term "non-aqueous" at all, either in independent or dependent claims.

Applicant also argues that Davis is disclosing a nebulizer whereas instant claims recite a metered dose inhalers. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Here Davis was combined with Weers, which is clearly teaching delivery of a bioactive agent via a metered dose inhaler.

Applicant argues that Weers is teaching a suspension formulation and not a solution. Again references cannot be attacked individually. Weers is a supporting art teaching fluticasone propionate and delivery via a metered dose inhaler. Davis is teaching formulations in a solution form.

Applicant argues that Otterbeck is teaching budesonide solutions for use as an enema or rectal foam, while the present claims are drawn to a HFA propellant systems

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for delivering fine particles of medicament to the lungs. This is not commensurate with the scope of claims. Instant claims are drawn to a metered dose inhaler comprising a solution formulation of fluticasone propionate and propellant. there is no delivery limitation in the said claims. Furthermore in a product claim site of delivery would be considered" intended use limitation" which is not given weight. Thus Otterbeck is proper prior art reciting a solution formulation which renders the instant formulations obvious.

The amended claim 2 recites a concentration range of 0.5 to 35 of a low volatility component. As shown in the rejection, Davis discloses formulations that comprise 5% propylene glycol which renders a concentration of 3% obvious. Furthermore optimization of ranges is obvious to one of ordinary skill in the art and **not** support for patentability.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

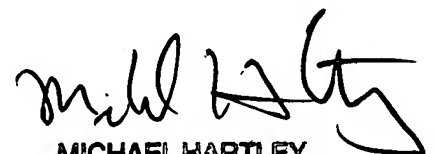
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mina Haghighatian
January 22, 2006



MICHAEL HARTLEY
PRIMARY EXAMINER